RELEASABLY-SECURABLE ONE-PIECE ADJUSTABLE GASTRIC BAND

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates generally to surgically implanted gastric bands for encircling the stomach having a releasable securing appendage. A method for treating morbid obesity utilizing a releasably-securable gastric banding device is also disclosed.

2. DESCRIPTION OF THE RELATED ART

A belt-like gastric band for encircling the stomach to control morbid obesity is disclosed by Vincent in U.S. Pat. 5,601,604, incorporated herein by reference. The band comprises a belt that can be passed around the stomach and locked into an encircling position in order to create a stoma opening within the stomach. An adjustable portion of the band comprises an inflatable member, which permits fine adjustment of the stoma opening after the stoma is created by locking the band in place. The stoma opening may be adjusted by adding or withdrawing a fluid into or from an inflatable member. The means for injecting the fluid into the inflatable member usually comprises a fill port located beneath the skin that can be accessed extracorporeally by transdermal injection. Thus, following implantation, the gastric band can be adjusted to enlarge or reduce the stoma as required.

The gastric band is implanted surgically, via laparoscopy or laparotomy, and may involve placement of a calibrating apparatus in the stomach to position the stoma and size the pouch created above the stoma. The gastric band is imbricated in position about the stomach to prevent slippage, usually by gastro-gastric sutures (*i.e.* tissue is wrapped over the band and sutured to itself).

As disclosed by Vincent, the inflatable member or shell is preferably substantially coextensive with an inner stomach-facing surface of the gastric band. Furthermore, it has been observed that the inflatable member should not wrinkle or fold when adjusted, so as to present a substantially smooth contour along the inner circumference. This ensures not only that stomach tissue will not be pinched by the inflatable member, which could lead to discomfort or necrosis, but also protects the shell from a phenomenon known as crease fold failure, which may occur if it is inflated beyond its intended range of adjustment or if the shell is not formed in a toroidal or circular shape.

In use, it has been observed that current gastric bands cannot be easily released once they are locked in place around the stomach to form the stoma. This can be a significant setback for a surgeon attempting to move a gastric band after implantation. In particular, a patients' physiology or change in physiology may necessitate moving the band after initial placement. Other factors that could require moving or releasing the band include a patient's inability to control food intake.

In instances where the band has slid out of place, is improperly placed, or where changes in patient physiology require movement of the band, the currently known gastric bands do not provide for releasing the locking means that hold the band securely around a patient's stomach. While some devices may ultimately be releasable, such devices typically require exertion of considerable force, which can cause damage to or failure of the band. Further, when manipulating the band laparoscopically, the amount of force that can be applied during such a procedure is very limited.

One gastric banding device that appears to have some ability to be locked and unlocked has been marketed under the name HELIOGAST®. The Heliogast band is an

inflatable gastric band having an inflatable locking means attached to the tail and which is inserted into a loop attached to the head of the band. After implantation, the band must be inflated to lock the band in place. In theory, this band could be re-opened after placement to allow a medical professional to reposition the band. However, it suffers from the drawback that it must be inflated to lock into position and therefore it must be deflated before being opened and moved. The requirement that the band must be inflated to lock also limits the range of the stoma opening that can be achieved by such a band, as the band must necessarily have a certain amount of liquid pressure inside the band in order to lock. Consequently, the range of adjustment of the Heliogast band is limited in comparison with the band of the present invention, which can be locked regardless of its inflation level. In addition the band can be opened by application of a smaller force than those of the prior art. The smaller force's ability to overcome the locking mechanism increases the possibility of the band unlocking accidentally, such as during vomiting by the patient.

Accordingly, there is a need for a releasable gastric band that can be releasably locked in place around a patient's stomach, released or unlocked to reposition the gastric band on the patient's stomach (or remove the band altogether), and then secured in place again around the patient's stomach. There is further a need for a releasably-securable gastric band that does not require deflation before being released, and which may be locked in place without subsequent inflation of the locking means. Additionally, there is a need for a gastric band that resists being unlocked by normal physiological forces

There is also a need for an adjustable gastric band with increased ease of use when compared to those currently on the international market, specifically a gastric band that has

high tensile force resistance along the band, while being able to be opened with reduced force.

Various other objects, advantages and features of the present invention will become readily apparent from the ensuing description and the novel features will be particularly pointed out in the appended claims.

SUMMARY OF THE INVENTION

The present invention is directed to a releasably-securable inflatable gastric band having a tail end and a head end for receiving the tail end. The gastric band also includes a releasable locking means that releasably secures the head and tail ends together. The tail end may include a tooth and the head end may include a notch for engaging the tooth. Upon insertion of the tail end into the head end, the tooth mates with the notch and releasably locks the tail end in the head end. The releasably-securable gastric band may also include a release tab. When force is applied to the release tab in a direction perpendicular to a central axis of the gastric band, the release tab acts on the tooth and the tooth is moved from the notch. This movement of the tooth from the notch allows the gastric band to open.

The various features of novelty that characterize the invention are pointed out in particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects attained by its uses, reference is made to the accompanying descriptive matter in which preferred embodiments of the invention are illustrated.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a tail end of a gastric band according to the present invention;

FIG. 2 is a side view of a head end of a gastric band according to the present invention;

FIG. 3 depicts a gastric band according to the present invention having a smooth inflatable member;

FIG. 4 depicts a fatigue resistant inflatable member of a gastric band;

FIG. 5 depicts a prior art gastric band according to U.S. Pat. 5,601,604 to Vincent;

FIG. 6 is a perspective view of a gastric band according to the present invention showing the head end in the foreground; and

FIG. 7 is a perspective view of a gastric band according to the present invention showing the tail end in the foreground.

DETAILED DESCRIPTION

The present invention is directed to a laparoscopic implantable adjustable gastric band designed to be opened or released laparoscopically in order to facilitate repositioning or removal when necessary. Once locked in position, previously known laparoscopic gastric bands, such as the LAP-BAND®, can only be opened with difficulty and at the risk of damaging the components due to the force required. While particularly suited to laparoscopic implantation, release and/or removal, the gastric band of the present invention is also suitable for standard laparotomy procedures.

Turning now to Figs. 1 and 7, there is shown a tail end 10a of a releasably-securable gastric band 12. In Figs. 2 and 6, the head end 10b of gastric band 12 is depicted. The tail end 10a comprises a elongated tip 18, which may incorporate an inflation tube 30, and a sloped tooth 14. Inflation tube 30 has a lumen therethrough to allow fluid to be added to or removed from the an inflatable portion of the band 32 to hydraulically adjust the diameter of

the band when it is in an encircling position about the stomach or desired organ. As is well known in the art, a stoma of desired size may be by created by adjusting the diameter of the gastric band. The adjustment may be carried out hydraulically or mechanically. In a hydraulically-adjustable gastric band, inflation tube 30 need not be incorporated into tail end 10a. Instead, it may be incorporated at head end 10b or at any point in between. Alternatively, gastric band 12 may be adjusted through a variety of known mechanical means. Whether hydraulic or mechanical, gastric band 12 is preferably adjusted via remote control from outside the body. Such remote adjustable restriction devices may be active devices, *i.e.* powered by implantable sources of energy such as batteries, capacitors, etc. or passive devices powered from outside the body by energy transferred through radio frequency, induction, electromagnetic energy, etc.

Turning back to the releasably locking features of the present invention, tooth 14 is defined on one side by a notch 16, and may include a visual indicator 38, which will be discussed below in conjunction with the head end 10b. Also shown in Fig. 1 is the adjustable portion of the band 32. Formed on the head end 10a of the gastric band 12 is a gripping land 34, which allows the surgeon or other medical professional to grip the gastric band 12 without fear of damaging the fluid bearing portions of the band. The gripping land 34 is especially helpful when releasing a previously locked gastric band.

The head end 10b, as shown in Fig. 2, includes a buckle 20 that receives and locks the tail end 10a to form the band in an encircling position about the stomach. The buckle 20 includes a notch 22 for receiving the tooth 14 of the tail end 10a. The head end 10b further comprises a release tab 24. Another aspect of the head end 10b is the indicator window 36, which allows the surgeon or other medical professional to view the indictor 38 portion of

the tail end 10a, preferably enhanced by a contrasting color or texture, when inserted into the head end 10b to provide positive visual and/or tactile indication that the gastric band had been releasably locked in position.

In practice, the gastric band is implanted around the stomach of the patient using now-standard laparoscopic or laparotomic procedures well known by those of skill in the gastric banding art. Once the gastric band 12 encircles the stomach and is positioned in the desired location along the length of the stomach, the tail end 10a is inserted into the buckle 20 of the head end 10b. A closure tool, such as that described in U.S. Patent No. 5,658,298 to Vincent and Coe, the disclosure of which is incorporated herein by reference, may be used to secure the tail and head ends, 10a and 10b respectively, together. For example, the tail end 10a is drawn through the buckle 20 until the tooth 14 and the notch 22 engage or interlock and prevent the gastric band 12 from opening. When the two ends of the gastric band are properly locked together, the indicator 38 on the tail end 10a is visible through window 36 on the head end 10b.

Further elements of the gastric band 12 are the mating recesses 26 and 28 of the head and tail ends 10a and 10b respectively. These recesses, which are substantially the negative image of one another, butt together and prevent the overlap of the two ends of the inner stomach-facing surface 32 of the gastric band when the band is in its closed position. The recesses 26 and 28 are formed on the head and tail ends respectively to ensure a substantially smooth continuous surface contacts the patient's stomach.

The releasably-securable gastric band according to the present invention requires a two-step procedure to release its locking head and tail ends. First the interlocking tooth 14 and notch 20 are disengaged by pulling on the release tab 24 in a direction substantially

perpendicular to a central axis of the now-closed gastric band 12. To assist in pulling on the release tab 24, the surgeon or other medical professional may also grasp the gripping land 34 with a second medical instrument. Doing so helps hold the gastric band 12 in place so that force can be efficiently applied to the release tab 24. Next, the tail 10a may be removed from the head end 10b if the band is to be removed or loosened sufficiently to allow the gastric band 12 to be repositioned along the length of the patient's stomach.

Through the use of a slightly elongated head end 10b, as compared to the LAP-BAND® of the prior art and U.S. Patent No. 5,601,604, pulling on the release tab 24 causes a translational force toward the central axis of the gastric band 12, thereby unlocking and releasing the head and tail ends of the gastric band 12 of the present invention to permit repositioning or removal of the gastric band 12 without fear of damaging the gastric band. Both the fit of the tooth 14 and recess 20, and the elasticity of the materials from which the gastric band are made can be optimized to ensure a sufficiently secure closure of the gastric band that requires relatively little force on the release tab 24 to open.

Naturally, geometries other than the tooth 14 and notch 22 may be used to achieve the ability to releasably secure the band in accordance with the present invention. One such geometry includes multiple smaller interlocking elements. Further, the locking elements could be shaped for a "pop-fit" to provide tactile indication that the band is secured in place or if greater resistance to disengagement is desired.

The present invention may be used in conjunction with a substantially smooth adjustable member 32, as shown in Fig. 3, and known in the art. Alternatively, the present invention may be used in conjunction with a newer fatigue-resistant inflatable member 32a, as shown in Fig. 4. A fatigue resistant band is described in detail in PCT/US03/26678 and

is incorporated herein by reference. As described therein, the fatigue resistant inflatable portion 32a is multi-chambered and resistant to wrinkling or folding over its range of adjustment. Like the adjustable portion 32 shown in Fig. 3, the fatigue resistant inflatable portion 32a presents a substantially smooth contour along the inner circumference to promote the comfort of the wearer and avoid pinching of the stomach that can lead to necrosis. The fatigue resistant inflatable member is shown in cross-section in Fig. 4 separate from a complete gastric band to better illustrate its novel features. As with previous bands, a gastric band comprising a fatigue resistant inflatable portion 32a can be pre-formed in a circle, can be locked in place by the surgeon or medical professional, and in one preferred embodiment is inflated via an inflation lumen running through the tail end 10a of the gastric band.

Gastric bands according to the present invention may be constructed in sequential molding steps, resulting in a fully automated assembly and a high degree of precision. Further, the materials from which the gastric band may be made include silicone and other materials known to those of skill in the art as compatible for implantation within the body.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, because certain changes may be made in carrying out the above method and in the construction(s) set forth without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.